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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124496
Facility ID: 202226
Inspection ID #2022260007

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

March 17, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bruce Hillman, M.D., Chairman
Orange Diagnostic and Mammography Center
661 University Lane
Suite D
Orange, Virginia 22960

Dear Dr. Hillman:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on March 6, 2000. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding:

- **Quality control records for the breast phantom were missing for a period of 4 weeks for the [redacted] unit located in your mammography suite.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as a Level 1 finding because it identifies a failure to comply with a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, your response should address the following Level 2 finding that was listed on the inspection report:

- **Two of ten randomly reviewed mammography reports did not contain an assessment category.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: David J. Gallant,
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District